

Remarks

Claims 12 and 20-25 are currently pending and under examination. Claims 1-8, 10, 13-19 have been cancelled. As a preliminary matter, the Examiner has indicated that Applicants must affirm to election of SEQ ID NO:1. Applicants do so, but note that the cancellation of the relevant claims also makes this election moot. The Examiner has also objected to the specification and claims. The relevant paragraphs of the specification have been amended, and the objected to claims have been cancelled. Finally, the cover page for the office action indicates that the drawings have been objected to. However, the office action does not indicate for what reason the drawings have been objected to. Nevertheless, Applicants have attempted to address the drawings by removing sheets 8 and 14 in the drawing set accompanying this communication. If the Examiner indicates why the drawings are objected to, the Applicants will endeavor to comply with the Examiner's request.

The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claims 3, 5, 8, 12, 14, and 16 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite;
2. Claims 12, 15 and 16 are rejected under 35 U.S.C. §112, first paragraph, as allegedly being not enabled;
3. Claims 12, 15 and 16 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description;
4. Claims 1, 2, 3, 5, 7, 8, 12, 14, 15, 16, and 19 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Harper et al., U.S. Pat. Pub. 2002/0160378.

Unless otherwise noted, the claims have been cancelled or amended to further Applicant's business interests and the prosecution of the present application in a manner consistent with the PTO's Patent Business Goals (PBG; 65 Fed. Reg. 54603 (September 8, 2000)), and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future. None of the claim amendments made herein are intended to narrow the scope of any of the amended claims within the meaning of *Festo Corp. v. Shoketsu*

Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) or related cases.

1. The Claims Are Not Indefinite

Claims 3, 5, 8, 12, 14, and 16 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is moot with respect to cancelled claims 3, 5, 8, 14, and 16. Claim 12 has been amended to refer to genes that are 85% homologous, thus the rejection for use of the term “sufficiently homologous” is traversed.

2. The Claims Are Enabled

Claims 12, 15 and 16 are rejected under 35 U.S.C. §112, first paragraph, as allegedly being not enabled. Claim 12 is currently pending, and claims 15 and 16 have been cancelled. Thus, Applicants address only the rejection of Claim 12.

Applicants respectfully disagree with the Examiner. The Examiner argues that “Claims 12, 15, and 16 encompass deleted or functionally altered domains for an encoded transcription regulating protein that is either substantially similar or at least 85% but less than 100% identical to SEQ ID NO:1 except for differences due to genetic code degeneracy. Undue experimentation would be required by a skilled artisan to determine the sequences or regions of SEQ ID NO:1 that can be altered, and what to change them to, without affecting functional activity.”

Applicant contends that the Examiner has not established a *prima facie* case of nonenablement. The standard to be applied in assessing enablement is whether the experimentation needed to practice the claimed invention is undue or unreasonable. *See* TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH-ENABLEMENT CHEMICAL/BIOTECHNICAL APPLICATIONS, *citing In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). When applying this standard, the burden is on the Examiner to make a *prima facie* case of non-enablement that is well grounded in scientific reasoning or evidence. *See In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993); *See also* MPEP §706.03 and §2164.04. This is because without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling (*Wright*, 27 USPQ2d at 1513).

Claim 12 specifically provides that the transcription regulating protein is both at least

85% homologous to SEQ ID NO:1 and that that “the protein is capable of selectively binding to a DNA regulatory sequence comprising CAACA in the plant which regulates expression of one or more environmental stress tolerance genes in the plant.” Thus, the claims provide a functional limitation that is easily tested by one of skill in the art. The Examiner’s arguments do not take this functional limitation into consideration. Applicants respectfully submit that, given the teachings of the specification, one of skill in the art would be able to easily identify functional variants that can bind to a DNA regulatory sequence comprising CAACA in a plant. Because the Examiner has not considered this limitation, the Examiner’s argument is not well grounded in scientific reasoning or fact and a *prima facie* case of nonenablement has not been established.

3. The Claims Have An Adequate Written Description

Claims 12, 15 and 16 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description. Claim 12 is currently pending, and claims 15 and 16 have been cancelled. Thus, Applicants address only the rejection of Claim 12.

The Examiner argues that “the specification fails to describe all such DNA encoding transcription regulating protein structures that are either substantially similar or at least 85% but less than 100% identical to SEQ ID NO:1.” Office Action pg. 7. Applicants respectfully submit that this is not the standard required by the Federal Circuit in *Eli Lilly* or in the USPTO own guidelines.

Applicants respectfully refer the Examiner to the USPTO’s “Synopsis of Application of Written Description Guidelines”, Example 14, pages 53-55. The claim of Example 14 recites a protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A->B. The disclosure of Example 14 provides a single species (SEQ ID NO:3) that has actually been reduced to practice, and describes an assay for identifying the variants having the desired catalytic activity. The analysis considers (1) whether the members of genus vary substantially from each other; and (2) whether the disclosed species is representative of the members of the genus; in order to determine whether one of skill in the art would determine if the applicant was in possession of the necessary common attributes possessed by the members of the genus.

For Example 14, it was determined that the member species did not substantially vary since the variants have 95% identity or greater to the reference sequence, and also possess the

catalytic activity. It was also determined that the disclosed species was representative since all members must have at least 95% structural identity to SEQ ID NO:3. The analysis determined that one of skill in the art would conclude that the applicant was in possession of the necessary common attributes possessed by the members of the genus, and therefore the disclosure in this Example meets the written description requirement.

Applicants submit that the subject matter of Claim 12 of instant application can be analyzed in a similar manner to that provided in Example 14 of the Written Description Guidelines. Claim 12 requires 1) at least 85% homology to SEQ ID NO:1 and 2) that “the protein is capable of selectively binding to a DNA regulatory sequence comprising CAACA in the plant which regulates expression of one or more environmental stress tolerance genes in the plant.” In Claim 12, just as in the Written Description Guidelines, the disclosed species is representative because all members of the genus must have 85% homology and because they must exhibit binding to a defined sequence.

The Examiner has ignored this limitation as evidenced by the argument that “Keeping in view the well established fact that stable structure characteristics are vital for any transcription regulating protein to function through DNA binding with a DNA element, it becomes reasonably evident that applicants have not actually reduced their invention to practice.” This argument completely ignores the fact that the claims require binding to a particular element!

Claim 12 is precisely analogous to the Written Description Guidelines where the disclosed species was 95% identical had a required catalytic activity. This is all the USPTO’s Written Description Guidelines and the law require. Thus, this ground of rejection should be removed.

4. The Claims Are Not Anticipated

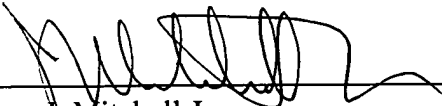
The Examiner has rejected Claims 1, 2, 3, 5, 7, 8, 12, 14, 15, 16, and 19 under 35 U.S.C. §102(e) as allegedly being anticipated by Harper et al., U.S. Pat. Pub. 2002/0160378. In making this rejection, the Examiner argues that Harper et al. teach expressing SEQ ID NO:2316, which is identical to SEQ ID No. 1 of the instant application, to induce “stress tolerance in transgenic plant, wherein said stress includes freezing, drought and other types of environmental stresses. See page 5, paragraph 0031, page 10, paragraph 0054. Also see claims 29, 33, 35, 46, 47, 49, 51, 52, 53 and 55.” Office Action pg. 9.

The paragraphs and claims cited by the Examiner do not indicate the specific function of SEQ ID NO:2316, and thus only describe generic functions without attributing a specific function to the gene. When the actual data is analyzed, it becomes clear that Harper et al. do not teach the use of SEQ ID NO:1 of the instant application for inducing freezing or drought tolerance. The Examiner's attention is respectfully directed to Column 80, table 7 of Harper et al. SEQ ID NO:2316 is identified in Table 7 as being a saline stress responsive sequence. SEQ ID NO:2316 is not identified as a cold responsive sequence in Table 3 (columns 72-75) or as an osmotic stress related sequence in Table 11 (column 82), or as cold and saline responsive sequence in Table 18 (column 86). Thus, Harper et al. does not teach the use of SEQ ID NO:2316 to induce freezing and drought tolerance. The Harper et al. application teaches away from these use and instead only teaches use of saline stress response. The instant Applicants have thus identified new uses for SEQ ID NO:1. Indeed, from the instant Applicants data, it appears that the Harper et al. data is incorrect.

Conclusion

All grounds of rejection and objection of the Office Action of November 4, 2005 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: February 6, 2006



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